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| 10/542,509 | 01/06/2006 | David Strand | 005092-00075 | 5918 |
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| BALL, JOHN C | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,509

Applicant(s)

STRAND ET AL.

Examiner

J. CHRISTOPHER BALL

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date 02/27/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. This is the initial Office Action based on the of the STRAND et al. application filed under the Patent Cooperation Treaty on January 12, 2004, and entered the National Stage with a filing with the Office on January 6, 2006.
2. Per the Preliminary Amendment filed with the Office on July 15, 2005, claims 1-17 and 24 are currently pending and have been fully considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: permeable member, referred to as "16" on pg 62, second paragraph of the specification, does not appear in Figure 23. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: None of the reference numbers for elements referred to in Figure 20 appear in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3, 5, 11-17, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 9, 13-17, 19, 57, 60 and 70 of copending Application No. 10/537,197 (US PGPUB 2007/0235335 A1; herein after referred to as "Copending") in view of IVORY et al. (US 6,277,258).

The limitations of instant claim 1 are all taught by Copending claims 1, 9 and 13, except that the limitation of "hydrodynamic force of sample fluid flow along the flow path through the separation chamber" is not taught by the claims of the Copending. However, IVORY teaches this limitation (Col. 5, lines 10-15).

It would be obvious to one of ordinary skill in the art to modify the claims of the Copending to include the hydrodynamic flow as taught by IVORY because it allows charged molecules to focus in order of their apparent electrophoretic mobilities (IVORY, Col. 5, lines 15-18).

The limitations of instant claims 2 and 3 are taught by the Copending claim 1.

The limitations of instant claim 5 are taught by the Copending claims 17 and 19.

The limitations of instant claims 11-15 are taught by the Copending claim 14.

The limitations of instant claim 16 are taught by the Copending claim 15.

The limitations of instant claim 17 are taught by the Copending claim 16.

The limitations of instant claim 24 are all taught by Copending claims 57, 60, and 70, except that the limitation of "hydrodynamic force of sample fluid flow along the flow path through the separation chamber" is not taught by the claims of the Copending. However, IVORY teaches this limitation (Col. 5, lines 10-15). It would be obvious to one of ordinary skill in the art to modify the claims of the Copending to include the hydrodynamic flow as taught by IVORY because it allows charged molecules to focus in order of their apparent electrophoretic mobilities (IVORY, Col. 5, lines 15-18).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5-7, 11-13, 15, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by IVORY et al. (US 6,277,258), submitted to the Office on an information disclosure statement.

Regarding claim 1, Ivory et al. discloses an electrophoresis device for focusing a charged analyte (Abstract; Figures 1 and 4) comprising: a separation chamber (12) having inlet and outlet ports (114 and 116) defining a flow path for sample fluid (Column 8, lines 17-19); electrodes (22) separated from the separation chamber by a membrane (16) and operative to generate an electric field gradient in the separation chamber (Column 5, lines 10-30); and molecular sieve in the separation chamber operative to shift the location at which a stationary focused band of analyte forms under a given set of focusing parameters including at least the electric field gradient and the hydrodynamic force of sample fluid flow (Column 5, lines 10-30; Column 6, lines 30-44; Column 8, lines 18-21).

Regarding claim 2, IVORY teaches a gradient in the electric field. (Column 5, lines 10-16).

Regarding claim 3, IVORY teaches an electrode chamber (14) containing the electrodes (22) and separated from the separation chamber by a permeable membrane (16) (Column 5, lines 39-44).

Regarding claim 5, IVORY teaches an electrode array (Column 8, lines 8-10).

Regarding claim 6, IVORY teaches individual control of the electrodes (Column 6, lines 9-12) .

Regarding claim 7, IVORY teaches dynamic control of the electric field gradient generated by the electrode array (Column 6, lines 9-12).

Regarding claims 11-13 and 15, IVORY teaches the sieve comprising a gel, an organic gel, an inorganic gel, and a soluble gel (Column 6, lines 30-44; Table 4).

Regarding claim 24, IVORY teaches a method for focusing a charged analyte comprising: providing an electrophoresis device as described in claim 1

(Column 19, line 34 - column 21, line 31; and see treatment above), and introducing a flow of sample fluid into the separation chamber, the sample fluid comprising the analyte (Column 21, lines 36-37); energizing at least a subset of the electrodes to establish an electric field gradient in the separation chamber effective to focus the analyte in the separation chamber (Column 21, lines 37-49).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of IVORY et al. (US 5,298,143; herein after referred to as "IVORY B"), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claims 1 and 3, as outlined above.

IVORY does not disclose a device wherein the electrode chamber is non-uniform and the separation chamber is encircled longitudinally by the electrode chamber.

However, IVORY B disclose a similar electrophoresis device (Figure 20) in which the electrode chamber (650) is nonuniform (varying cross-section) and encircles the separation chamber (653) longitudinally.

At the time of the present invention, it would have been obvious to one having ordinary skill in the art to modify the device of IVORY by configuring the system cylindrically with a non-uniform electrode chamber, as taught by IVORY B because it gives more membrane surface area for removal of low-molecular weight impurities and a more uniform electric field in the separation chamber.

12. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of IVORY et al. (US 5,298,143; herein after referred to as "IVORY B"), an article by KOEGLER et al. ("Focusing proteins in an electric field gradient", JOURNAL OF CHROMATOGRAPHY A, vol. 726, no. 1-2, March 1996, p. 229-236), and a portion of a book by LI (Capillary

Electrophoresis Principles, Practice, and Applications, New York: Elsevier Science Publications, 1992, pp. 192-200), all submitted to the Office on an information disclosure statement.

IVORY teaches the limitations of claim 1, as outlined above. IVORY additionally teaches the dependence of band position on the electrophoretic mobility of an analyte. (Column 14, lines 16-33).

IVORY does not specifically disclose devices or methods whereby the position shift of the focused band of analyte for a given set of conditions varies by molecular weight, as recited in claim 8, molecular size as recited in claim 9, or is proportional to the molecular weight as recited in claim 10.

However, KOEGLER and IVORY B disclose a theory describing the mechanism of separation in an electric field gradient focusing apparatus such as those disclosed by IVORY, suggesting dependence of mobility on molecular size and density.

Additionally, LI discloses the dependence of electrophoretic mobility of proteins on their molecular mass, and discusses the use of polyacrylamide gel electrophoresis to separate proteins based on mass. (Page 192)

At the time of the present invention, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device and method of IVORY by using a gel that separates analytes on the basis of molecular size or molecular weight, as taught by KOEGLER and IVORY B,

because it would give a separation with higher resolution. And, given the teachings of LI, the separation of the analytes would be proportional to their molecular weight, among other variables.

13. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of ANDERSON et al. (US 5,993,627), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claims 1 and 11, as outlined above.

IVORY does not explicitly teach the use of a fixed gel.

However, ANDERSON discloses the use of cast slab gels, which are fixed in molds (Column 8, lines 27-31, 50-53).

At the time of the present invention, it would have been obvious to one having ordinary skill in the art to modify the device of IVORY by using a gel fixed within the separation chamber, as taught by ANDERSON, because it would allow collection of purified protein with minimal contamination from the separation matrix.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of MENCHEN et al. (US 5,759,369), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claims 1 and 11, as outlined above.

IVORY does not explicitly teach the use of a gel having molecules with molecular weight between 2000 and 100,000 Da.

However, MENCHEN discloses a viscous polymer medium for use in electrophoresis, which contains molecules having molecular weight in the range of 4-500 kDa (Column 9, lines 63-67).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of IVORY by selecting a gel with molecular weight within the range of 4-100 kDa, as taught by MENCHEN, because IVORY suggest the suitability of a broad range of media (including polymer solutions) for use in their device (Column 6, lines 30-44).

15. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over IVORY et al. (6,277,258) in view of WILSON et al. (US 5,019,232), both submitted to the Office on an information disclosure statement.

IVORY teaches all the limitations of claim 1, as outlined above.

IVORY does not explicitly teach the use of a molecular sieve comprising zeolite.

However, WILSON discloses a medium for electrophoresis comprising polymer fibrils, particulate support, and a modifier such as zeolite (Column 6, lines 1-10).

It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of IVORY by using a molecular sieve comprising zeolite, as taught by WILSON, because IVORY suggest the suitability of a broad range of media (including porous particulate chromatography packings) for use in the described device (Column 6, lines 30-44).

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

JCB
07/23/2009